Application No. 09/068,751

DRAFT CLAIMS FOR INTERVIEW 2/12/03

83. A recombinant virus vector comprising two terminal repeat sequences and a packaging signal of said virus, and a promoter nucleic acid fragment of a mammalian myosin light chain gene,

wherein the promoter nucleic acid fragment is operatively linked to the terminal repeat sequences and packaging signal of said virus and is effective for cardiac tissue specific expression of the nucleic acid sequence to be expressed under conditions of somatic gene transfer.

84. The recombinant virus vector of claim 83, wherein the promoter nucleic acid fragment comprises nucleotides of approximately residue -19 to approximately residue -2700, with respect to the transcription starting point, of the mammalian myosin light chain gene.

85. A recombinant virus vector comprising [a] the virus vector pAD-mlc. (alternatively, "... comprising the vector deposited in the cell line ATCC #####").

86. The recombinant virus vector of claim 83, in which the virus vector is an adenovirus vector, an adeno-associated virus vector or a replication deficient adenovirus vector.

87. The recombinant virus vector of claim 84, in which the virus vector is an adenovirus vector, an adeno-associated virus vector or a replication deficient adenovirus vector.

88. The recombinant virus vector according to claim 86, wherein the virus vector is a replication deficient adenovirus vector comprising two inverted terminal repeat sequences (ITR) of the adenovirus.

89. The recombinant virus vector according to claim 87, wherein the virus vector is a replication deficient adenovirus vector comprising two inverted terminal repeat sequences (ITR) of the adenovirus.

90. The recombinant virus vector according to claim 86, wherein the virus vector is a replication deficient adenovirus vector consisting of two inverted terminal repeat sequences (ITR) of the adenovirus.

91. The recombinant virus vector according to claim 87, wherein the virus vector is a replication deficient adenovirus

vector consisting of two inverted terminal repeat sequences (ITR) of the adenovirus.

92. The recombinant virus vector of any one of claims 83 to 91, further comprising a desired nucleic acid to be expressed that is operatively linked to said promoter.

93. The recombinant virus vector according to claim 92, wherein the nucleic acid sequence to be expressed encodes a proteinaceous gene product.

94. The recombinant virus vector according to claim 93, wherein the proteinaceous gene product is selected from a dystrophin, a ß adrenergic receptor or a nitric oxide synthetase.

95. The recombinant virus vector according to claim 92, wherein the nucleic acid sequence to be expressed encodes an antisense nucleic acid or a ribozyme.

96. A recombinant virus vector comprising two repeat sequences and a packaging signal of said virus, and a promoter nucleic acid fragment comprising the regulatory elements:

HF 1a and 1b consisting of nucleotides of a mammalian mlc2 promoter corresponding to nucleotides 2340 to 2361 of SEQ ID NO:1;

MLE1 consisting of nucleotides of a mammalian mlc2 promoter corresponding to nucleotides 2229 to 2241 of SEQ ID NO: 1; and

HF 3 consisting of nucleotides of a mammalian mlc2 promoter corresponding to nucleotides 2207 to 2219 of SEQ ID NO: 1; an E box element consisting of nucleotides 2328 to 2333 of SEQ ID NO: 1; and optionally

an HF 2 element consisting of nucleotides of a mammalian mlc2 promoter corresponding to nucleotides 2271 to 2289 of SEQ ID NO: 1;

wherein the promoter nucleic acid fragment is operatively linked to the two terminal repeat sequences and the packaging signal of said virus and is effective for cardiac tissue specific expression of the nucleic acid sequence to be expressed under conditions of somatic gene transfer.

97. The recombinant virus vector of claim 96, further comprising a CSS element consisting of nucleotides of a mammalian mlc2 promoter corresponding to nucleotides 682 to 724 of SEQ ID NO: 1.

103. The recombinant virus vector according to claim 99, wherein the virus vector is a replication deficient adenovirus vector consisting of two inverted terminal repeat sequences (ITR) of the adenovirus.

104. The recombinant virus vector of any one of claims 96 to 103, further comprising a desired nucleic acid to be expressed that is operatively linked to said promoter.

105. The recombinant virus vector according to claim 104, wherein the nucleic acid sequence to be expressed encodes a proteinaceous gene product.

106. The recombinant virus vector according to claim 105, wherein the proteinaceous gene product is selected from a dystrophin, a ß adrenergic receptor or a nitric oxide synthetase.

107. The recombinant virus vector according to claim 104, wherein the nucleic acid sequence to be expressed encodes an antisense nucleic acid or a ribozyme.

108. A composition comprising the recombinant virus vector of any one of claims 92-95, complexed with liposomes.

98. The recombinant virus vector of claim 96, in which the virus vector is an adenovirus vector, an adeno-associated virus vector or a replication deficient adenovirus vector.

99. The recombinant virus vector of claim 97, in which the virus vector is an adenovirus vector, an adeno-associated virus vector or a replication deficient adenovirus vector.

100. The recombinant virus vector according to claim 98, wherein the virus vector is a replication deficient adenovirus vector comprising two inverted terminal repeat sequences (ITR) of the adenovirus.

101. The recombinant virus vector according to claim 99, wherein the virus vector is a replication deficient adenovirus vector comprising two inverted terminal repeat sequences (ITR) of the adenovirus.

102. The recombinant virus vector according to claim 98, wherein the virus vector is a replication deficient adenovirus vector consisting of two inverted terminal repeat sequences (ITR) of the adenovirus.

109. A composition comprising the recombinant virus vector of claim 104, complexed with liposomes.

110. A composition comprising the recombinant virus vector of claim 105, complexed with liposomes.

111. A composition comprising the recombinant virus vector of claim 106, complexed with liposomes.

112. A composition comprising the recombinant virus vector of claim 107, complexed with liposomes.

113. A composition comprising the recombinant virus vector of any of claims 92-95 and a pharmaceutically acceptable carrier.

114. A composition comprising the recombinant virus vector of claim 104 and a pharmaceutically acceptable carrier.

115. A composition comprising the recombinant virus vector of claim 105 and a pharmaceutically acceptable carrier.

116. A composition comprising the recombinant virus vector of claim 106 and a pharmaceutically acceptable carrier.

117. A composition comprising the recombinant virus vector of claim 116 and a pharmaceutically acceptable carrier.

118. A method for delivery of a desired gene to cardiac muscle cells of a subject, which method comprises administering a recombinant virus vector according to any one of claims 92-95, optionally complexed with liposomes, to cardiac tissue, heart blood vessels or the heart cavity of a subject, thereby delivering the desired gene to the cardiac muscle cells of the subject.

119. A method for delivery of a desired gene to cardiac muscle cells of a subject, which method comprises administering a recombinant virus vector according to claim 104, optionally complexed with liposomes, to cardiac tissue, heart blood vessels or the heart cavity of a subject, thereby delivering the desired gene to the cardiac muscle cells of the subject.

120. A method for delivery of a desired gene to cardiac muscle cells of a subject, which method comprises administering a recombinant virus vector according to any one of claims 105, optionally complexed with liposomes, to cardiac tissue, heart blood vessels or the heart cavity of a subject, thereby

delivering the desired gene to the cardiac muscle cells of the subject.

121. A method for delivery of a desired gene to cardiac muscle cells of a subject, which method comprises administering a recombinant virus vector according to any one of claims 106, optionally complexed with liposomes, to cardiac tissue, heart blood vessels or the heart cavity of a subject, thereby delivering the desired gene to the cardiac muscle cells of the subject.

122. A method for delivery of a desired gene to cardiac muscle cells of a subject, which method comprises administering a recombinant virus vector according to any one of claims 107, optionally complexed with liposomes, to cardiac tissue, heart blood vessels or the heart cavity of a subject, thereby delivering the desired gene to the cardiac muscle cells of the subject.

123. The method of claim 118, wherein the subject presents a heart disease selected from the group consisting of a heart insufficiency, dilative or hypertrophic cardiomyopathy, dystrophinopathy, vessel disorder, high blood pressure,

atherosclerosis, stenosis of a blood vessel, or restenosis of a blood vessel.

124. The method of claim 119, wherein the subject presents a heart disease selected from the group consisting of a heart insufficiency, dilative or hypertrophic cardiomyopathy, dystrophinopathy, vessel disorder, high blood pressure, atherosclerosis, stenosis of a blood vessel, or restenosis of a blood vessel.

125. The method of claim 119, wherein the subject presents a heart disease selected from the group consisting of a heart insufficiency, dilative or hypertrophic cardiomyopathy, dystrophinopathy, vessel disorder, high blood pressure, atherosclerosis, stenosis of a blood vessel, or restenosis of a blood vessel.

126. The method of claim 120, wherein the subject presents a heart disease selected from the group consisting of a heart insufficiency, dilative or hypertrophic cardiomyopathy, dystrophinopathy, vessel disorder, high blood pressure, atherosclerosis, stenosis of a blood vessel, or restenosis of a blood vessel.

127. The method of claim 121, wherein the subject presents a heart disease selected from the group consisting of a heart insufficiency, dilative or hypertrophic cardiomyopathy, dystrophinopathy, vessel disorder, high blood pressure, atherosclerosis, stenosis of a blood vessel, or restenosis of a blood vessel.